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(54) **FASTENER INSERTION METHOD**

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        CPC *A61B 17/8886* (2013.01); *A61B 17/86* (2013.01); *A61B 17/866* (2013.01); *A61B 17/8875* (2013.01); *A61B 2019/307* (2013.01); *B25B 23/1415* (2013.01); *A61B 17/861* (2013.01)

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(57)   **ABSTRACT**

A method is provided and may include rotating a biocompatible, non-metallic threaded fastener at a rotational speed greater than 15,000 revolutions per minute and driving said fastener into a bone at said rotational speed.

20 Claims, 2 Drawing Sheets
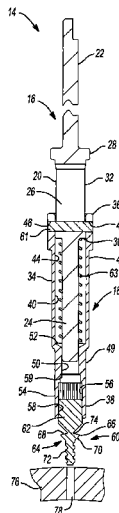
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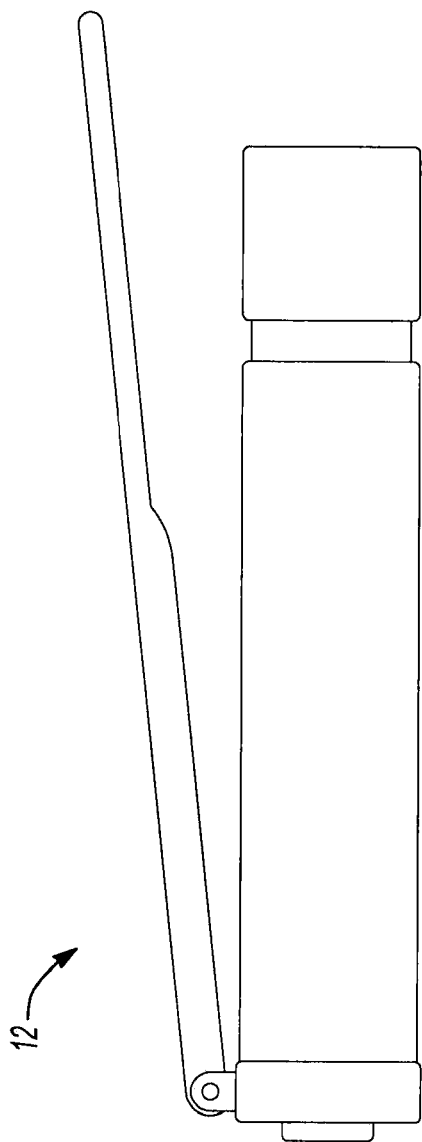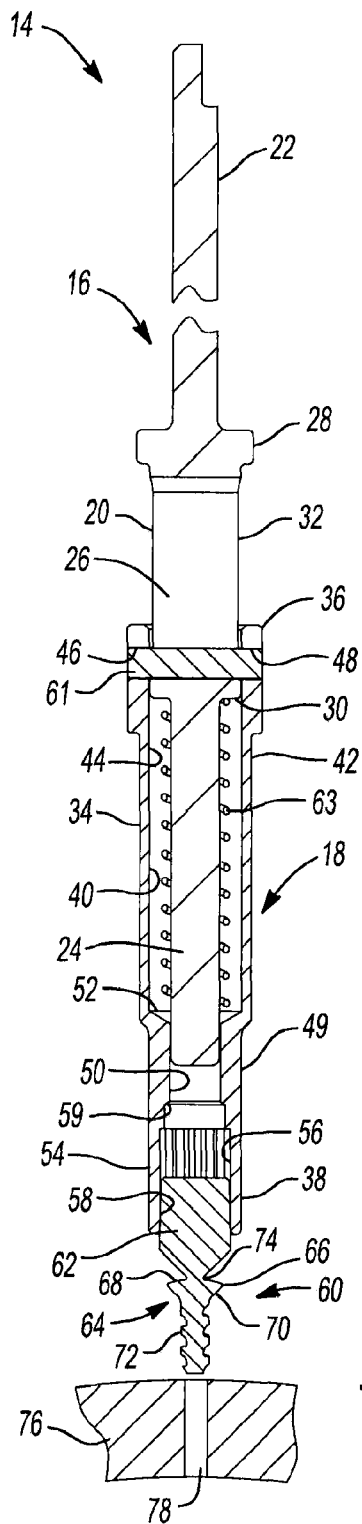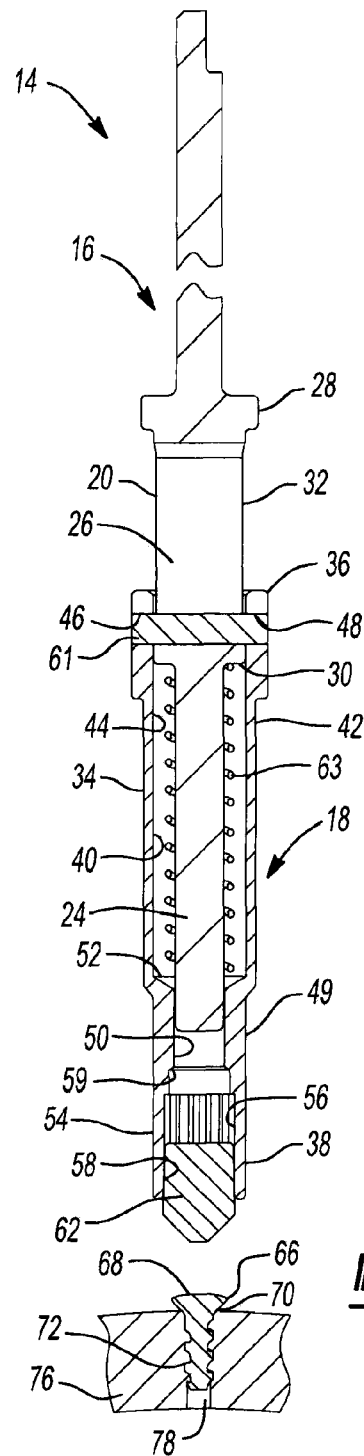
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Fig - 1

Fig-2

Fig-3

FASTENER INSERTION METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 12/040,310, filed on Feb. 29, 2008, which claims the benefit of U.S. Provisional Application No. 60/905,157, filed on Mar. 6, 2007, and U.S. Provisional Application No. 60/904,678, filed on Mar. 2, 2007. The disclosures of each of the above applications are incorporated herein by reference.

FIELD

The present disclosure relates to threaded fasteners, and more specifically to insertion methods for threaded fasteners.

BACKGROUND

The statements in this section merely provide background information related to the present disclosure and may not constitute prior art.

Typical fastener insertion techniques may include applying a torque to a threaded fastener to rotationally drive the fastener into a structure. The torsional strength of the fastener is typically greater than the torque applied to drive the fastener to prevent breaking of the fastener before insertion is completed. The torque applied to the fastener increases when a self-tapping fastener is used due to the additional force required to cut threads into the structure.

SUMMARY

A method is provided and may include rotating a biocompatible, non-metallic threaded fastener at a rotational speed greater than 15,000 revolutions per minute and driving said fastener into a bone at said rotational speed.

Further areas of applicability will become apparent from the description provided herein. It should be understood that the description and specific examples are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.

DRAWINGS

The drawings described herein are for illustration purposes only and are not intended to limit the scope of the present disclosure in any way.

FIG. 1 is a perspective view of a powered driver according to the present disclosure;

FIG. 2 is a translucent plan view of an adapter assembly and fastener according to the present disclosure; and

FIG. 3 is an additional translucent plan view of the adapter assembly and fastener of FIG. 2.

DETAILED DESCRIPTION

The following description is merely exemplary in nature and is not intended to limit the present disclosure, application, or uses.

With reference to FIGS. 1-3, a driving assembly for a fastener may include a powered driver 12 and an adapter assembly 14. Powered driver 12 may be any driver capable of driving adapter assembly 14 in the manner discussed below. Powered driver 12 shown in FIG. 1 is a powered driver from

MicroAire Surgical Instruments L.L.C. of Charlottesville, Va. Adapter assembly 14 may be engaged with and driven by powered driver 12.

More specifically, adapter assembly 14 may include a plunger 16 and a driving member 18. Plunger 16 may include a central body portion 20, a connection shank 22, and an ejector shaft 24. Central body portion 20 may include a generally cylindrical body 26 having first and second ends 28, 30. An elongate passage 32 may extend radially through cylindrical body 26 and may have an axial extent along cylindrical body 26. Connection shank 22 may extend axially from first end 28 of cylindrical body 26 and may engage powered driver 12 for driving adapter assembly 14. Ejector shaft 24 may be generally cylindrical or may be in the form of a drill bit for drilling a pilot hole, as discussed below, and may extend axially from second end 30 of cylindrical body 26 and may be slidably disposed within driving member 18, as discussed below.

Driving member 18 may include an elongate body 34 having first and second ends 36, 38. A central opening 40 may extend axially through elongate body 34 and first and second ends 36, 38. A first portion 42 of elongate body 34 may include a first portion 44 of central opening 40 passing therethrough. First portion 44 of central opening 40 may extend through first end 36 and may have a first diameter greater than the diameter of a central portion of cylindrical body 26 and second end 30 thereof and less than the diameter of first end 28 of cylindrical body 26. A set of apertures 46, 48 may extend radially through first portion 42 of driving member 18 near first end 36.

A second portion 49 of elongate body 34 may include a second portion 50 of central opening 40 passing therethrough. Second portion 50 of central opening 40 may have a second diameter that is less than the first diameter of first portion 44, forming a step 52 therebetween. The second diameter of second portion 50 may be greater than the diameter of ejector shaft 24 and less than the diameter of cylindrical body 26 of plunger 16.

A third portion 54 of elongate body 34 may include a driving geometry. More specifically, third portion 54 may include a third portion 56 of central opening 40 extending therethrough. Third portion 56 may extend through second end 38 of driving member 18 and may define a series of flats 58 or some other form of driving geometry on an inner wall of third portion 56. Third portion 56 of central opening 40 may have a third diameter that is greater than the second diameter of second portion 50, forming a step 59 therebetween.

Cylindrical body 26 may be disposed in first portion 44 of central opening 40 and a pin 61 may pass through apertures 46, 48 in driving member 18 and elongate passage 32 in plunger 16, slidably coupling plunger 16 to driving member 18. Ejector shaft 24 may extend into first and second portions 44, 50 of central opening 40 when plunger 16 is in a retracted position (seen in FIGS. 2 and 3) and may be extended into third portion 56 of central opening 40 to abut and/or eject a fastener 60, as discussed below. A spring 63 may be engaged with step 52 and second end 30 of cylindrical body 26, urging plunger 16 into the retracted position.

Fastener 60 may be disposed within third portion 56 of central opening 40. Fastener 60 may include a torque limiting feature, such as first and second portions that are removable from one another when a predetermined torque limit is exceeded. For example, the first portion may include a breakaway portion 62 and the second portion may include a fastening portion 64. Breakaway portion 62 may be coupled to fastening portion 64 and may include a series of flats engaged with flats 58 within third portion 56 of central opening 40,

providing for driving of fastener **60** by the driving assembly. Breakaway portion **62** may be retained within third portion **56** of central opening **40** through an interference fit engagement therewith. Fastening portion **64** may include a head **66** having upper and lower portions **68**, **70** and a threaded shank **72**. Breakaway portion **62** may be integrally formed with and coupled to upper portion **68** of head **66** at a reduced diameter breakaway region **74** and threaded shank **72** may extend from lower portion **70**. A series of recesses (not shown) may be formed in a perimeter of head **66**.

Fastener **60** may be formed from a variety of materials including, but not limited to metals (including titanium, titanium alloys, stainless steel, zirconium, and CoCr), biocompatible non-resorbable materials (including polyetheretherketone (PEEK) and polyetherketoneketone (PEKK)), biocompatible resorbable materials, ceramics, composite materials, allograft or xenograft (including demineralized bone matrix and coral), or combinations thereof.

The fasteners and fastener insertion method discussed below may include a variety of applications such as to craniofacial procedures, neurosurgical procedures, spinal procedures, orthopedic procedures, suture anchors (Glencord anchors), small bone fixation/anchors, anterior cruciate ligament (ACL) fixation devices (tendon repair devices), and soft tissue anchors. Further, while discussed with respect to powered driver **12**, adapter assembly **14**, and fastener **60**, it is understood that a variety of alternate driving assemblies and fasteners may be used as well.

As seen in FIGS. **2** and **3**, fastener **60** may be fixed to another structure **76** such as bone, wood, or some other media. A pilot hole **78** may be drilled into structure **76** and fastener **60** may be inserted into pilot hole **78**. More specifically, fastener **60** may cut threads into pilot hole **78**. Fastener **60** may therefore act as a self tapping screw. In order to insert a self-tapping screw, work is performed on the screw. Work is generally defined as a force imparted over a distance:

$$\text{Work}=F_i\times D;$$

where F_i is force and D is distance.

In the context of the present disclosure, the force (F_i) noted above in the work definition may generally include a sum of the force (F_c) needed to cut (or tap) threads and the force of friction (F_{f1}) from the threads on structure **76**. The driving assembly may apply the force (F_i) to fastener **60** in order to insert fastener **60** into pilot hole **78**. The force (F_s) applied by fastener **60** may generally include the sum of the force (F_t) from the torque imparted on fastener **60** and the force (F_k) from the kinetic energy of fastener **60**. Therefore, in order to insert fastener **60** into structure **76**, force (F_e) should be greater than force (F_i). When fastener **60** is inserted at low rotational speeds, the kinetic energy force component (F_k) may be small relative to the torque force component (F_t).

Kinetic energy is generally defined as:

$$K=\tfrac{1}{2}I\omega^2;$$

where K is kinetic energy, I is moment of inertia, and w is angular rotational velocity. Angular rotational velocity is directly proportional to rotational speed. Therefore, the kinetic energy force component (F_k) may be directly proportional to the square of the rotational speed that fastener **60** is being driven at. As rotational speed of fastener **60** increases, the torque force component (F_t) needed to drive fastener **60** into structure **76** may be reduced. More specifically, fastener **60** may be driven at a rotational speed that reduces the torque force component (F_t) required to drive fastener **60** into structure **76** below the torsional strength of fastener **60**. As such, fastener **60** may cut threads into structure **76**, even where

structure **76** has a torsional resistance that is greater than the torsional strength of fastener **60**.

However, once fastener **60** is fully inserted into structure **76** and head **66** abuts structure **76**, the force (F_i) required to further insert fastener **60** into structure **76** may be increased by the force of friction (F_{f2}) from head **66** on structure **76**. In order to maintain rotation of fastener **60**, force (F_s) must be increased. If the rotational speed that fastener **60** is being driven at remains constant, the torque force component (F_t) increases. Once the torque force component (F_t) exceeds the torsional strength of breakaway region **74**, breakaway portion **62** may be separated from fastening portion **64**. Alternatively, some other torque limiting feature of fastener **60** or the driving assembly may prevent further transmission of driving torque to fastening portion **64**.

However, the force (F_s) applied to drive fastener **60** may be limited such that it is greater than the sum of the force (F_c) needed to cut (or tap) threads and the force of friction (F_{f1}) from the threads on structure **76**, but less than a strip-out force (F_{so}), ($F_{so}>F_s>F_c+F_{f1}$). Strip-out may occur when fastener **60** is located within structure **76** and rotationally driven without further insertion into structure **76**. In order to avoid a strip-out condition once fastener **60** is inserted into structure **76** and fastener head **66** is seated against structure **76**, the force applied to fastener **60** (F_s) may be limited such that it is less than the sum of the force (F_c) needed to cut (or tap) threads, the force of friction (F_{f1}) from the threads on structure **76**, and the force of friction (F_{f2}) from head **66** on structure **76**, which is less than the strip-out force (F_{so}), ($F_{so}>F_c+F_{f1}+F_{f2}>F_s$).

While discussed with regard to pilot hole **78**, the arrangement discussed above may also be used where fastener **60** is a self-drilling fastener and there is no pilot hole. In the self-drilling configuration, the discussion above applies equally, except the force (F_i) needed to drive fastener **60** may be increased by a drilling force (F_d). Accordingly, the kinetic energy force component (F_k) of fastener **60** may also be increased in order to keep the torque force component (F_t) below the torsional strength of fastener **60**.

Pilot hole **78** may have a diameter that is greater than the minor diameter and less than the major diameter of fastener **60**. The rotational speed needed to drive fastener **60** may vary based on the relation between the size of pilot hole **78**, the major diameter of fastener **60**, the length of threaded shank **72**, and the material density of structure **76** relative to the material density of fastener **60**.

More specifically, as the diameter of pilot hole **78** is increased, the rotational speed needed to drive fastener **60** is reduced and as the diameter of pilot hole **78** is decreased, the rotational speed needed to drive fastener **60** is increased. Similarly, as the length of threaded shank **72** is increased, the rotational speed needed to drive fastener **60** is increased and as the length of threaded shank **72** is decreased, the rotational speed needed to drive fastener **60** is decreased. As the material density of structure **76** is increased relative to the material density of fastener **60**, the rotational speed needed to drive fastener **60** is increased and as the material density of structure **76** is decreased relative to the material density of fastener **60**, the rotational speed needed to drive fastener **60** is decreased.

In operation, adapter assembly **14** may be coupled to powered driver **12** and a desired driving speed may be selected for powered driver **12**. Fastener **60** may be loaded into adapter assembly **14** and an end of fastener **60** may be placed against an opening of pilot hole **78** and fastener **60** may be axially aligned with pilot hole **78**. Fastener **60** may then be driven into pilot hole **78**, as discussed above.

More specifically, powered driver **12** may be rapidly actuated, rather than gradually actuated, to quickly generate a desired rotational speed. Downward force may be applied to fastener **60** by displacement of plunger **16** into engagement with fastener **60** once powered driver **12** has been actuated to achieve the desired rotational speed to drive fastener **60** into structure **76**. Fastener **60** may be formed from a material that has a greater or lesser torsional strength than the torsional resistance of structure **76**. However, even when fastener **60** is formed from a material having a lesser torsional strength than the torsional resistance of structure **76**, fastener **60** may still be driven into pilot hole **78** and may tap pilot hole **78** due to the kinetic energy force component (F_k) and the torque force component (F_t) of fastener **60**, as discussed above.

More specifically, when fastener **60** is driven into pilot hole **78** at a high rotational speed, the force (F_s) applied by fastener **60** may be great enough to tap structure **76**, such as bone. As indicated above, when the rotational speed of fastener **60** is great enough, the kinetic energy force component (F_k) may reduce the torque force component (F_t) needed to drive fastener **60** to a level below the torsional strength of fastener **60**. Since the entire fastener **60** (breakaway portion **62** and fastening portion **64**) is rotating at the high rotational speed, a minimal amount of torque is transmitted through fastener **60**, allowing fastener **60** to cut threads into structure **76** even when structure **76** has a torsional resistance that is greater than the torsional strength of fastener **60**.

As discussed above, once head **66** of fastener **60** bottoms out on an outer surface of structure **76**, an amount of torque required to drive fastener **60** further into structure **76** becomes too great for the kinetic energy force component (F_k) of fastener **60** and the torque force component (F_t) is increased. Torque may then be transmitted to breakaway region **74** causing breakaway portion **62** to separate from fastening portion **64**. Powered driver **12** may then be turned off and breakaway portion **62** may then be ejected from adapter assembly **14** through use of ejector shaft **24**.

Several parameters may be varied for driving fastener **60** in the method discussed above. For example, parameters that may be used for the appropriate fastener and driving arrangement according to the method described above may include the major and minor diameters of the threaded shank **72**, the body length of threaded shank **72**, the pilot hole diameter, the downward force applied to fastener **60**, the speed ramp up of powered driver **12**, the set speed of powered driver **12**, rate of trigger actuation of powered driver **12**, and the material properties of structure **76** and fastener **60**, such as material densities. More specifically, Table 1 below includes several configurations and associated parameter values for driving fastener **60** in the manner discussed above. The configurations listed below are examples and may generally apply to structure **76** being bone and fastener **60** being formed from a polymer. As indicated above, fastener **60** may be formed from a material that has a greater or lesser torsional strength than the torsional resistance of structure **76**. In the examples listed below, the polymer formed fastener **60** may have a torsional strength less than the torsional resistance of bone.

TABLE 1

major diameter (mm)	body length (mm)	pilot hole diameter (mm)	driver speed (rpm)
1.5	5	1.3	12,000
1.5	3	1.1	20,000
1.5	4	1.1	25,000-30,000
1.5	4	1.2	25,000-30,000

TABLE 1-continued

major diameter (mm)	body length (mm)	pilot hole diameter (mm)	driver speed (rpm)
1.5	5	1.1	25,000-30,000
1.5	5	1.2	25,000-30,000
1.5	8	1.3	25,000-30,000

What is claimed is:

1. A method comprising:
rotating a biocompatible, non-metallic threaded fastener at a rotational speed greater than 15,000 revolutions per minute; and
driving said fastener into a bone at said rotational speed, said fastener being formed from a material that is softer than said bone.

2. The method of claim **1**, wherein rotating said biocompatible, non-metallic threaded fastener includes rotating a fastener formed from one of a polymer, a biocompatible non-resorbable material, a biocompatible resorbable material, a ceramic, a composite material, an allograft and a xenograft.

3. The method of claim **1**, further comprising terminating said driving when a predetermined torque limit is applied to said fastener.

4. The method of claim **3**, further comprising separating a first portion of said fastener from a second portion of said fastener when said predetermined torque limit is applied to said fastener.

5. The method of claim **1**, further comprising separating a first portion of said fastener from a second portion of said fastener when a predetermined torque limit is applied to said fastener.

6. The method of claim **1**, further comprising forming a pilot hole having a first diameter greater than a minor diameter of said fastener and less than a major diameter of said fastener, said driving including driving said fastener into said pilot hole.

7. The method of claim **1**, wherein a drilling force is applied to said fastener as said fastener is driven into said bone, a total force applied by said fastener being greater than the force required for said cutting and said drilling.

8. The method of claim **1**, wherein the first rotational speed is at least 25,000 revolutions per minute.

9. The method of claim **1**, wherein said material of said fastener is has a torsional strength that is less than a torsional resistance of said bone.

10. A method comprising driving a biocompatible, non-metallic threaded fastener at a rotational speed greater than 15,000 revolutions per minute into a bone, said rotational speed being based on a material density of said bone relative to a material density of said fastener.

11. The method of claim **10**, wherein said fastener is formed from a material that is softer than said bone.

12. The method of claim **10**, wherein said material of said fastener is has a torsional strength that is less than a torsional resistance of said bone.

13. The method of claim **12**, further comprising terminating said driving when a predetermined torque limit is applied to said fastener.

14. The method of claim **13**, further comprising separating a first portion of said fastener from a second portion of said fastener when said predetermined torque limit is applied to said fastener.

15. The method of claim **14**, further comprising forming a pilot hole having a first diameter greater than a minor diam-

eter of said fastener and less than a major diameter of said fastener, said driving including driving said fastener into said pilot hole.

16. A method comprising:

a step for rotating a fastener at a rotational speed greater than 15,000 revolutions per minute; and

a step for driving said fastener into a bone at said rotational speed, said fastener being formed from a material that is softer than said bone.

17. The method of claim 16, wherein said material of said fastener is has a torsional strength that is less than a torsional resistance of said bone.

18. The method of claim 16, further comprising a step for terminating said driving when a predetermined torque limit is applied to said fastener.

19. The method of claim 18, further comprising a step for separating a first portion of said fastener from a second portion of said fastener when said predetermined torque limit is applied to said fastener.

20. The method of claim 16, further comprising a step for forming a pilot hole having a first diameter greater than a minor diameter of said fastener and less than a major diameter of said fastener, said step for driving including driving said fastener into said pilot hole.

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